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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER

MARX, IRENE

ART UNIT PAPER NUMBER

1651

DATE MAILED: 10/16/2002

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.
09/830,894

Applicant(s)
Ju

Examiner
Irene Marx

Art Unit
1651



-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on Jul 31, 2002.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-71 is/are pending in the application.
- 4a) Of the above, claim(s) 35-71 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-34 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
*See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s). 4 6) ☐ Other:

The application should be reviewed for errors.

Applicant's election with traverse of Group I, claims 1-34 and 71 in Paper No. 7 is acknowledged. The traversal is on the ground(s) that the Group I claims are directed to a process that utilizes both aerobic and anaerobic respiration. However, the traverse does not address the specifics or the basis of the restriction requirement made. The restriction made is based on the particulars of the culturing conditions which are "aerobic" and "anaerobic", respectively, not on microbial respiration. The claims in group I, the elected invention, are directed to a process of culturing under aerobic conditions, since the medium is aerated with oxygen.

In addition, applicants argue that burden has not been demonstrated. For purposes of the initial restriction requirement a serious burden on the examiner may be *prima facie* shown if the examiner shows by appropriate explanation either separate classification, separate status in the art, or a different field of search as defined in MPEP 808.02. That *prima facie* showing may be rebutted by appropriate showings or evidence by the applicant. Applicant has not provided such evidence to demonstrate error in the restriction requirement.

The methods are of a different scope and the references which would be applied to one method would not necessarily anticipate or render obvious the other method.

Clearly different searches and issues are involved with each group.

For these reasons, the restriction requirement is deemed proper and is adhered to. The restriction requirement is hereby made FINAL. .

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 1-34 and 71 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1 is vague and indefinite in the recitation of "allowing the culture medium to incubate for a time sufficient to produce a desired quantity of a biological product". It is unclear

that incubating the "culture medium" is sufficient to produce a "desired quantity" of an undetermined product. In the instant case neither the conditions nor the genus/species of microorganisms to be cultured is claim designated. Moreover the "biological product" is similarly unidentified.

The "selection" process used is not clearly delineated in claim 1. In addition, It is uncertain how "an alternative oxidant" is identified for any and all microorganisms, the nature of which is not determined.

Inasmuch as the claims as written are directed to a process using mixed cultures of microorganisms, one of ordinary skill in the art cannot determine the process conditions with any specificity or particularity.

In addition, claim 31 is confusing in the use of a cellular concentration for inoculation of 50 g/l.

Claim 6 is vague and indefinite in the requirement that bacteria such as *Clostridium* or *Desulfovibrio* be "facultative aerobe". These bacteria are strict anaerobes. Therefore, the claim appears incorrect.

In addition, the genus "*Acidianus*" is not recognized. Clarification is required.

Claim 5 is objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form. It is submitted that to carry out the process of claim 1 a microorganism must be a facultative aerobe.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless --

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1-6, 10, 16 are rejected under 35 U.S.C. 102(b) as being anticipated by Varma *et al.*.

The claims are directed to the production of a biological product with a microorganism in the presence of an alternative oxidant source under aerobic conditions.

The claims are directed to the production of a biological product with a microorganism including bacteria, yeasts, molds and archaea in the presence of an alternative oxidant source under aerobic conditions such that the strain may utilize the alternative oxidant source.

Varma *et al.* disclose the production of cells of the microorganism *E. coli* in the presence of the alternative oxidant source acetate under aerobic conditions such that the strain uses the alternative oxidant source. See, e.g., page 3730, col. 2, paragraph 4 *et seq.*

Claims 1-10, 13, 15, 17-20, 22, 27-29, 31-34 are rejected under 35 U.S.C. 102(b) as being anticipated by Giani *et al.*.

The claims are directed to the production of a biological product with a microorganism in the presence of an alternative oxidant source under aerobic conditions.

The claims are directed to the production of a biological product with a microorganism including bacteria, yeasts, molds and archaea in the presence of an alternative oxidant source under aerobic conditions such that the strain may utilize the alternative oxidant source.

Giani *et al.* disclose the production of cells of the microorganism *Pseudomonas aeruginosa* in the presence of the alternative oxidant source NaNO_3 under aerobic conditions such that the strain uses the alternative oxidant source. See, e.g., col. 5, lines 25-67 and Example 1.

Claims 1-34 are rejected under 35 U.S.C. 103(a) as being unpatentable over Giani *et al.* taken with Brock and Wagner *et al.*

The claims are directed to the production of a biological product with a microorganism including bacteria, yeasts, molds and archaea in the presence of an alternative oxidant source under aerobic conditions such that the strain may utilize the alternative oxidant source.

As noted in the rejection under 35 U.S.C. § 102, *supra*, Giani *et al.* disclose the production of cells of the microorganism *Pseudomonas aeruginosa* in the presence of the alternative oxidant source NaNO_3 under aerobic conditions such that the strain uses the alternative oxidant source. See, e.g., col. 5, lines 25-67 and Example 1.

The reference differs from the claimed invention in that nitrate is the only oxidant or electron acceptor disclosed for anaerobic respiration. However, Brock discloses a variety of such oxidants, including fumarate, sulfate, sulfur, ferric ion and nitrite (See, e.g., pages 113-114).

The substitution of nitrate or another ion with of salts or acids as the source of the respective ion is deemed to be well within the ordinary skill in the art, particularly since the respective ions are generally provided as a salt in an aqueous nutrient medium environment.

The references further differ from the invention as claimed in the use of small acids or fatty acids in the medium. However, Wagner *et al.* adequately demonstrate that it is routine in the art to provide nutrient media containing small acids, such as malonate, succinate, pyruvate or malate, or fatty acids such as stearic acid for microorganisms, including *Pseudomonas*. (See, e.g., col. 3). The Wagner *et al.* reference also addresses the use of nutrient limitation in the cultivation of bacteria, specifically by limiting magnesium or nitrogen for the production of rhamnolipids with *Pseudomonas* (See, e.g., Examples 2-3).

One of ordinary skill in the art would have had a reasonable expectation of success in obtaining a biological product by cultivation of a microorganism in the presence of an alternative

oxidant source under aerobic conditions using a variety of carbon sources and the limitation of a variety of nutrients to boost yields of a desired product depending on the specific microorganism to be cultured and/or the product to be produced.

Therefore, it would have been obvious to one having ordinary skill in the art at the time the claimed invention was made to modify the process of cultivation of Giani *et al.* by the substitution of nitrate by other oxidants, as suggested by Brock as well as the use of nutrient limitation and various carbon substrates, as suggested by the teachings of Wagner *et al.* for the expected benefit of maximizing the production of useful biological products produced by microorganisms suitable for the pharmaceutical industries and for foods or feed, for example.


Thus, the claimed invention as a whole was clearly prima facie obvious, especially in the absence of evidence to the contrary.

No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Irene Marx whose telephone number is (703) 308-2922. The examiner can normally be reached on Monday through Friday from 6:30 AM to 3:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Wityshyn, can be reached on (703) 308-4743. The appropriate fax phone number for the organization where this application or proceeding is assigned is before final (703) 872-9306 and after final, (703) 872-9307.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to Customer Service whose telephone number is (703) 308-0198 or the receptionist whose telephone number is (703) 308-1235.


Irene Marx
Primary Examiner
Art Unit 1651